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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,052	06/21/2006	Yasuo Kunugiza	082368-007000US	8162

20350 7590 02/07/2008

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EXAMINER	
HAMA, JOANNE	

ART UNIT	PAPER NUMBER
1632	

MAIL DATE	DELIVERY MODE
02/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

TH

Office Action Summary	Application No.	Applicant(s)	
	10/570,052	KUNUGIZA ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6 and 9-14* is/are pending in the application.

4a) Of the above claim(s) *11 and 12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6,9,10,13 and 14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group 1 in the reply filed on November 19, 2007 is acknowledged. Applicant also elected, "DNA, oligonucleotide, RNA." With regard to the election of species, Applicant elects "elastic force of an elastic membrane" as the different way that the syringe injects a liquid, and "wound" as the skin disorder that is treated.

It is noted that the species of election of "elastic force of an elastic membrane" is withdrawn and species of gas pressure or elastic force will be examined. See Double Patenting and 103 rejection, below.

Claims 11, 12 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on November 19, 2007.

Claims 1, 6, 9, 10, 13, 14, drawn to a method for treating a skin disorder comprising introducing polynucleotide(s) encocing HGF and/or PGIS, using a needleless syringe, are under consideration.

Information Disclosure Statement

Applicant has filed Information Disclosure Statements (IDS) on June 21, 2006 and December 13, 2007. The IDSes have been considered.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 9, 10, 13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,247,620 ('620) in view of Slate et al., US Patent 6,406,456 ('456), patented June 18, 2002.

Claim 1 of '620 and instant claim 1 are similar in that they are both methods of treating wounded skin using a nucleic acid sequence encoding hepatocyte growth factor (HGF). While claim 1 of '620 does not specifically indicate that a needleless syringe be used to deliver the nucleic acid sequence, needleless syringes were known at the time of filing. Slate et al. teach an injector for delivery of a fluid medicament to a patient, wherein the medicament can be delivered intramuscularly, subcutaneously, or intradermally (Slate et al., abstract). Slate et al.'s syringe depends on pressure to

create a hole in the skin and deliver the medicament of interest (Slate et al., col., 2, 2nd parag.). It is noted that Slate et al. also indicate that their syringe can be used to deliver DNA (Slate et al., col. 2, line 26). As for delivery of the nucleic acid in multiple sites, it would be obvious to an artisan to use multiple injections of a nucleic acid construct comprising the nucleic acid sequence of HGF, particular if the wound is large.

With regard to species of wounds (claim 10 of the instant application, being drawn to include surgery), '620 teach that wounds were made in the backs of rats ('620, col. 12, line 65). Because '620 teach surgery, wounds made during a surgery are an obvious species.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6, 9, 10, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi et al., 2002, American Journal of Pathology, 161: 1761-1772 in view of Slate et al., US Patent 6,406,456 ('456), patented June 18, 2002.

Nakanishi et al. teach that a nucleic acid sequence encoding human hepatocyte growth factor (HGF) was introduced into skin wounds in rats. Nakanishi et al. teach that the wound lesion area in HGF gene-transferred rats was significantly less than control rats, from 3 to 7 days after gene transfer (Nakanishi et al., abstract). Nakanishi et al.

teach that expression vector comprising the nucleic acid sequence encoding HGF was mixed with HVJ liposomes and was injected via a syringe to wound sites in rats (Nakanishi et al., page 1762, under "Materials and Methods").

While Nakanishi et al. teach that a syringe was used to deliver an expression vector comprising a nucleic acid sequence encoding HGF, they do not teach a needleless syringe.

Slate et al. teach an injector for delivery of a fluid medicament to a patient, wherein the medicament can be delivered intramuscularly, subcutaneously, or intradermally (Slate et al., abstract). Slate et al.'s syringe depends on pressure to create a hole in the skin and deliver the medicament of interest (Slate et al., col., 2, 2nd parag.). It is noted that Slate et al. also indicate that their syringe can be used to deliver DNA (Slate et al., col. 2, line 26). As for delivery of the nucleic acid in multiple sites, it would be obvious to an artisan to use multiple injections of a nucleic acid construct comprising the nucleic acid sequence of HGF, particular if the wound is large.

Thus, it would have been obvious to an ordinary artisan to use a needleless injector, such as that taught by Slate et al., in the method of delivering a nucleic acid sequence encoding HGF to treat a skin wound. Slate et al. provide an alternative route of achieving Nakanishi et al.'s method of treating a skin wound, comprising administering a nucleic acid sequence encoding HGF.

Claims 13, 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakanishi et al., 2002, American Journal of Pathology, 161: 1761-1772 in view of Slate

et al., US Patent 6,406,456 ('456), patented June 18, 2002, in view of Yamamoto et al., 1996, European Journal of Pharmacology, 302, 53-60, in view of Gaine, 2000, JAMA, 284: 3160-3168, in view of Ullrich et al., 2001, Biochimica et Biophysica Acta, 1532: 1-14.

As discussed above, the art renders obvious a method of treating a skin disorder comprising introducing a polynucleotide comprising a nucleic acid sequence encoding HGF via a needleless syringe.

However, the combined teachings do not teach treatment of a skin disorder comprising introducing a polynucleotide comprising a nucleic acid sequence encoding PGIS via a needleless syringe.

Yamamoto et al. teach that a prostacyclin (PGI2) analog, SM-10902, could be used to treat skin wounds in mice (Yamamoto et al., abstract).

While Yamamoto et al. teach that SM-10902 can be used to treat skin wounds in mice, Yamamoto et al. do not teach using an expression vector comprising the coding region of prostacyclin synthase in skin wounds of mice.

Gaine teach that in addition to using prostacyclin analogs, such as epoprostenol and UT-15 to treat pulmonary hypertension, an artisan could use gene therapy of prostacyclin synthase (Gaine, page 3167, under "The Future" to page 3168).

Because Yamamoto et al. and Gaine teach ways of introducing alternate ways of introducing PGI2 in a patient, it would have been obvious to an ordinary artisan to use gene therapy, expressing prostacyclin synthase, in the wound model of Yamamoto et al.

(It is noted that prostacyclin synthase is the enzyme that process prostaglandind endoperoxidase H_2 to Prostaglandin I_2 (PGI_2), see for example, Ullrich, et al., Figure 1.)

As for combining the treatments of HGF and PGIS, both HGF and PGIS commonly have the ability to treat wounds. Therefore, combining two methods of treating wounds would be obvious to an ordinary artisan.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Joanne Hama
Art Unit 1632